Remarks/Arguments

The foregoing amendments in the claims are of formal nature, and do not add new matter. The Examiner had not entered the previous amendments (i.e. "isolated") indicating that it changed the scope of the claims. Applicants have canceled reference to this term in claim 39.

Claims 39-43 are presently pending in this application and are rejected under 35 U.S.C. §101 for lack of utility. This rejection is respectfully traversed.

Claim Rejections - 35 USC § 101

Claims 39-43 remain rejected under 35 U.S.C. §101 for lack of utility. The Examiner asserts that "the rejection is made for lack of a specific and substantial utility that does not require further experimentation to identify a real world use for the claimed invention." Even though the Examiner acknowledges that "the exhibits (previously presented) clearly demonstrates that (the) injection of PRO302 protein intra-dermally in guinea pigs will cause some vascular leakage, there is no convincing evidence or rational that PRO302 plays any role whatsoever in vascular leakage in its usual role(s) *in vivo.*" The Examiner adds "there is no convincing evidence or argument for a specific role for PRO302 in any condition that involves vascular integrity (e.g. pulmonary leakage, capillary leakage, tumor leakage or burns). Applicants respectfully traverse the rejection.

Utility Standard for "specific and substantial"

Under the Utility Guidelines, a utility is "specific" when it is particular to the subject matter claimed. For example, it is generally not enough to state that a nucleic acid is useful as a diagnostic without also identifying the conditions that is to be diagnosed.

The requirement of "substantial utility" defines a "real world" use, and derives from the Supreme Court's holding in *Brenner v. Manson*, 383 U.S. 519, 534 (1966) stating that "The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." In explaining the "substantial utility" standard, M.P.E.P. 2107.01 cautions, however, that Office personnel must be careful not to interpret the phrase "immediate benefit to the public" or similar formulations used in certain court decisions to mean that products or services based on the claimed invention must

be "currently available" to the public in order to satisfy the utility requirement. "Rather, any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a "substantial" utility." (M.P.E.P. 2107.01, emphasis added.) Indeed, the Guidelines for Examination of Applications for Compliance with the Utility Requirement, set forth in M.P.E.P, 2107 II (B) (1) gives the following instruction to patent examiners: **"If the (A)pplicant has asserted that the claimed invention is useful for any particular practical purpose . . . and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility."**

Arguments

Based on the positive results obtained in the vascular permeability assay, which the Examiner has acknowledged as true, Applicants had asserted a **specific and substantial** role for PRO302 where vascular leakage occurs like in pulmonary leakage, capillary leakage, tumor leakage or burns. However, since the Examiner maintains the rejection, without acquiescing to the propriety of the rejection, merely to expedite prosecution in this case, Applicants will shortly file an executed Declaration by Sherman Fong, Ph.D., an expert in the field of immunology, with discussions on the vascular leakage assay and how this assay identifies molecules that induce leakage, the mechanism of vascular leakage/permeability, how the assay and its modifications have been widely used in the art by several investigators in the identification of various well-established leak inducing molecules like VEGF (VPF) etc. and specific uses. Specific utilities for the PRO302 molecule and how such utilities would readily be understood and accepted as credible, substantial and specific, by those skilled in the art, will also be discussed by Dr. Fong in his declaration.

Accordingly, Applicants believe that the present rejection under 35 U.S.C. §101 and §112, first paragraph would be withdrawn.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C40). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: November 15, 2004

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